ORIGINAL ARTICLE

Comparison study between the usage of harmonic scalpel versus classical suture method for thyroidectomy in Iraqi patients

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Abstract

Objective: To compare the outcome of harmonic scalpel use in thyroid surgery versus conventional suture method in a sample of Iraqi patients

Methods: A prospective, comparative, interventional study with analytic elements was conducted on 76 patients complaining of different types of goitre attending Al-Yarmouk Teaching Hospital, Baghdad, from October 2017 to October 2019. Patients were divided into two groups, a test group including 25 patients operated upon by harmonic scalpel and the control group of 51 patients who underwent conventional suture ligation. Informed consent was obtained from all patients after explaining the procedure. The necessary investigations were done preoperatively with anaesthetic consultation. After surgery, type of thyroidectomy (Total, near total, subtotal, lobectomy), time of surgery, the results of the postoperative checkup including vital signs, voice state, any stridor or dyspnoea, drains (amount drained) and signs of hypocalcaemia were noted.

Results: The 76 patients were divided into 2 groups. Most of the patients were female (61 females, 23 in harmonic & 38 in conventional group" Vs. 15 males, 2 in harmonic & 13 in conventional group). The mean ages in both groups were comparable. The mean age was 40.0±9.7 years for conventional suture ligation group with females being 39.7±10.3 years and males being 40.8±7.9 years old. The mean age of patients in the harmonic scalpel group was 40.5±11.7 years with females being 40.4±12.5 years old and males 42.0±1.0 of age. Most of the HS devise patients had thyrotoxic goiter in comparison to simple goiter in the control group. The study shows a significant reduction in the time of surgery in the harmonic scalpel group, therefore most of them showed a significant reduction in the amount of blood in their drain and the drain was removed within 24 hours. Regarding the remaining post-operative complications like bleeding, stridor, and recurrent laryngeal nerve injury. The results had no statistical significant difference in both groups.

Conclusion: Both HS and ligation sutures were effective in thyroid surgery except the reduction in operation time and postoperative drainage in the HS group. Both techniques were taken as reasonably safe procedures.

Keywords: Thyroidectomy, Harmonic Scalpel, Classical Ligation, Suture hemorrhage, Recurrent laryngeal nerve injury. (JPMA 71: S-40 [Suppl. 8]; 2021)

Introduction

Thyroidectomy is the most frequent operation among endocrine surgery. There are different types of surgeries which include right or left or bilateral lobectomy for nodular goitre, subtotal or near-total for multinodular goitre (MNG) and Total thyroidectomy for malignant mass or a toxic goitre.[1,2] The old trail to manage goitre were disastrous with very high mortality and morbidity due to bleeding and airway obstruction. The advancement in surgery did not occur until the middle of the nineteenth century. In 1938 recurrent nerve palsies were recorded with a frequency as low as 0.3%. As the old methodology changed, another advancement in the 21st century saw a new concept by the introduction of vessel sealing devices.[3] These devices comprise of Harmonic Scalpel (HS) (Ethicon endosurgery, Inc., USA), ultrasonic cordless dissector by Covidien) which provides bloodless field and low complication rates. HS uses vibration rather than emitting heat at 55,000 Hz which disrupts hydrogen bonds of proteins leading to its rupture, and because the temperature induced is mild (80°C) in comparison to electrocautery. The proteoglycans and collagen fibers in the tissue become denatured and mix with the intracellular and interstitial fluids to form a glue-like substance (coagulum), which seals the 5 mm vessels providing haemostasis, equivalent to electrocautery.[4] Due to these advantages, HS has minimised surgical time with less intraoperative bleeding.[5] In comparision, tying a knot takes a longer surgical time and bipolar or monopolar diathermy has a high risk of nearby structures being damaged because of lateral thermal spread.[6] Studies have assessed the cost-effectiveness and hospital stay, time of operation for the HS but a drawback of these

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studies is that they have had different types of ultrasonic devices since their introduction in 2007. Studies are still discussing the effect of these devices on the parathyroid gland and recurrent laryngeal nerve function.[7] In Iraq, recently many surgeons have started to use these devices and record their data but still, some enquire about their safety and limitations related to extra cost burden on the patients and their availability in the government and private hospitals.

This study aims to compare the outcome of using the HS versus conventional suture method in a group of Iraqi patients.

Patients and Methods

A prospective interventional study with analytic elements was conducted on 76 selected patients complaining of different types of goiters. The sample size was calculated using the Epi-Info equation adopted by CDC taking in consideration the acceptable level of significance, power of the study, expected effect size, underlying event rate in the population, and standard deviation in the population.[8] The patients were selected from those who attended AL-YARMOUK teaching hospital, a governmental academic hospital in Baghdad, Iraq during the period October 2017 to October 2019. This period included recruitment, preparation, surgery, postoperative follow-up and data collection. Patients with recurrent goitre, retrosternal goitre and those requiring a thoracotomy approach were excluded. Only one case was treated by the cervical approach as the patient had a retrosternal extension in the anterior mediastinum. The technique was of careful finger release, and haemostasis was secured by HS surgery without the need for thoracotomy.

The inclusion criteria were:

1. Benign simple, toxic multinodular goiter.

2. Benign autoimmune thyroiditis with hypothyroidism and pressure symptoms.

3. Malignant thyroid nodule diagnosed by radiological and cytological aspiration.

The sample was divided into two groups. According to calculation of the specialty, the control subjects were required to be double the number of test patients to acquire acceptable comparision. It was also considered that the HS was not available all the time in the hospital. Thus two groups were formed. A test group comprised of 25 patients whose surgery was done using a harmonic scalpel (HS) and the control group included 51 patients who underwent conventional suture ligation (CSL). All patients were investigated preoperatively inclusive of thyroid function test (free T3, free T4 and TSH), serum calcium, radiological assessment by ultrasound study of the neck, chest X-ray, some cases needed CT scan of the thyroid gland, pulmonary function test, ECHO study and vocal cord mobility. Preoperative anaesthetic consultation was performed and informed consent for participation in the study was obtained.

The operation was done under General Anaesthesia by a transverse collar incision. The strap muscle was opened using HS in the test group and a dissecting scissor in the control group. Thyroid lobe was separated from strap muscles for both groups. Only in HS group, the Middle thyroid vein was identified and coagulated by HS. In the test group the vein was divided and ligated with vicryl 2/0 sutures. The same was done for upper and lower thyroid poles in both groups. Recurrent laryngeal nerves and parathyroid glands were identified and preserved. Haemostasias was secured without sutures by using a harmonic knife. Valsalva maneuver was performed, pillows removed from underneath, suction drain left in situ, and skin was closed. Type of thyroidectomy: (Total, near-total, subtotal, lobectomy) and time of surgery (from skin incision to the skin closure) was recorded. Postoperative checkup included vital signs, voice state, any stridor or dyspnoea, volume from drains and signs of hypocalcaemia (serum Ca level, any numbness and carpopedal spasm).

Statistical Analysis

Analysis of data was carried out using the statistical package of SPSS-25 (Statistical Packages for Social Sciences- version 25). Data were presented in simple measures of frequency, percentage, mean, standard deviation, and range (minimum-maximum values). The significance of difference of different percentages (qualitative data) was tested using the Pearson Chi-square test with an application of Yate's correction or Fisher Exact test wherever applicable. Statistical significance was considered when the p-value was equal to or less than 0.05.

Results

In the period of 2 years, 76 patients were included in this study. The test group with use of HS had 25 patients (23 females and 2 males). The control group of 51 patients (38 females and 13 males) were subjected to the ligation suture method. The indications and type of surgery for both groups are shown in Table-1. There was no significant difference regarding age (p= 0.420) and gender (p= 0.072) as shown in Figure-1. The mean age of patients operated by CLS was 40.0±9.7 (Range: 20-66) years while it was

Table-1: The indications, type and time of surgery for both groups.

		Harmonic Scalpel (n=25)		Ligation suture (n=51)		P value
		No	%	No	%	
Type of goiter	Simple	7	28.0	33	64.7	0.0001*
	Toxic	9	36.0	18	35.3	
	Hypothyroidism	2	8.0	-	-	
	Retrosternal	1	4.0	-	-	
	Benign	2	8.0	-	-	
	Malignant	4	16.0	-	-	
Type of surgery	Total	16	56.0	27	52.9	0.054
	Near total	6	24.0	14	27.5	
	Subtotal	2	8.0	10	19.5	
	Lobectomy	3	12.0	-	-	
Time of surgery (hours)	<1 hour	3	12.0	-	-	0.0001*
	1.0---	18	72.0	15	29.6	
	2.0---	4	16.0	32	62.6	
	=>3 hours	-	-	4	7.8	
Time of surgery (hours)		1.4±0.4 (45M-2:30H)		2.1±0.4 (1:30-3:00H)		

*Significant difference between proportions using Pearson Chi-square test at 0.05 level.

Table-2: Comparison of postoperative results of the patients.

		Harmonic Scalpel (n=25)		Ligation suture (n=51)		P value
		No	%	No	%	
Volume Drained	50-100 cc	17	68.0	3	5.9	0.0001*
	>100 cc	8	32.0	48	94.1	
Drain removal time	First post-op day	15	60.0	3	5.9	0.0001*
	2nd post-op day	10	40.0	48	94.1	
Haemorrahge	Yes	-	-	-	-	-
	No	25	100.0	51	100.0	
Hypocalcaemia	Yes	3	12.0	6	11.8	0.976
	No	22	88.0	45	88.2	
Fever	Yes	8	32.0	23	45.1	0.275
	No	17	68.0	28	54.9	
Stridor	Yes	1	4.0	1	2.0	0.602
	No	24	96.0	50	98.0	
Hoarsiness of voice	Yes	5	20.0	8	15.7	0.639
	No	20	80.0	43	84.3	
Injury to RLN	Unilateral	4	16.0	7	13.7	0.834
	Bilateral	1	4.0	1	2.0	
	No	20	80.0	43	54.3	

*Significant difference between proportions using Pearson Chi-square test at 0.05 level.RLN: Recurrent Laryngeal Nerve.

40.5±11.7 (Range: 20-60) years for patients operated by HS (p<0.05). The difference between the two groups was types of goitre and surgery. Seven (28%) of the test group compared to 33 (64.7%) patients of the control group had simple goitre (p< 0.0001). While the second significant difference was regarding the operation time, for the test group 18(72%) patients were through their operations within one hour, in comparison to the control group in which 32(62.7%) patients had a surgery duration of 2 hours. (p<0.0001) (Table-2). The postoperative results showed that the volume drained was more than 100 ml in the control group of 48(94.1%) patients compared to 8 (32%) patients in the test group, which was statistically significant (p< 0.0001). For this reason, 15 out of 25 (60%) patients operated by using HS had their drains removed earlier on 1st day. In the CSL group 48(94.1%) patients had their drains removed on 2nd post-operative day (p< 0.0001). There was no significant difference in the post-operative complications in both groups which included Hypocalcaemia, fever, stridor, hoarseness of voice and recurrent laryngeal nerve (RLN) injury (Figure-2). The results are presented in Table-2.

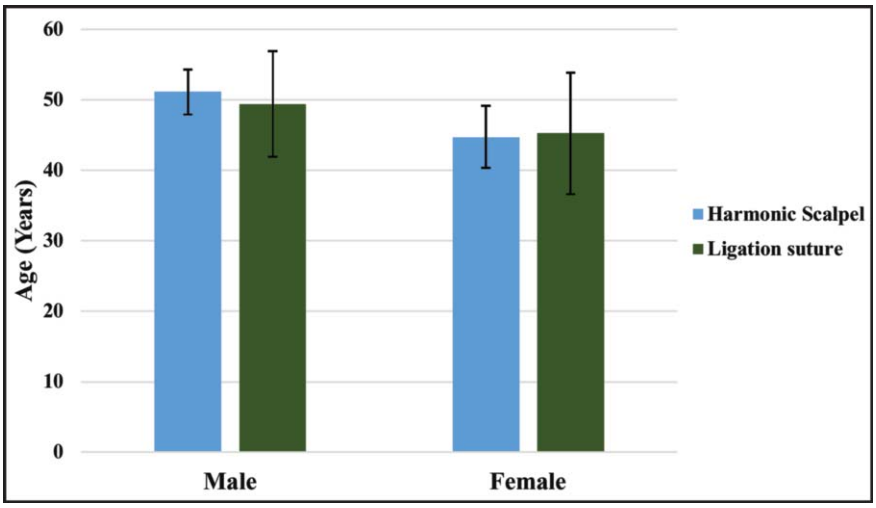

Figure-1: Comparison of age in males and females for both Harmonic scalpel and ligation suture.

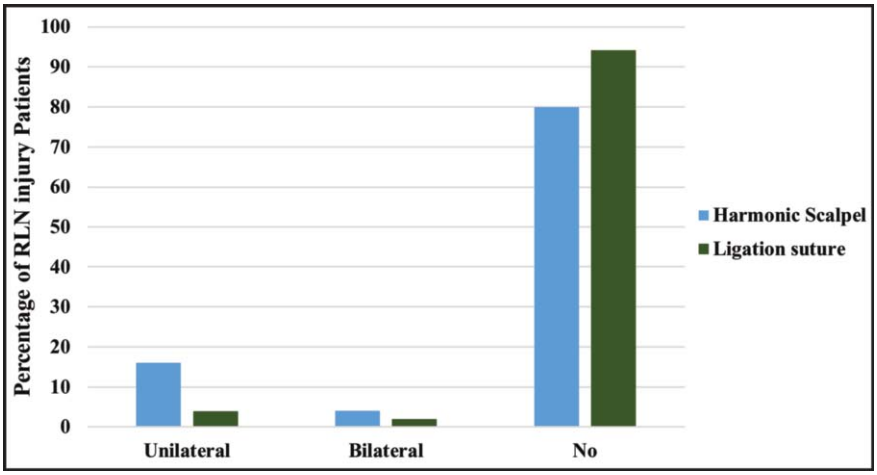

Figure-2: Comparison of Patients with RLN injury for both Harmonic scalpel and ligation suture.

Discussion

Thyroidectomy is a surgical procedure with low morbidity and no mortality but requires careful search of anatomical details and good and secure haemostasis.[8] Harmonic Scalpel, recently used successfully by general surgeons in laparoscopic abdominal surgery has been recently introduced in thyroidectomy and other neck surgeries,[9] HS was found to seal arteries with an average diameter of 3.8-9.9 mm.[10] Heat burn is confined to 0-2mm beyond the tissue grasped within the forceps, therefore lower lateral thermal damage can occur when compared to bipolar diathermy.[11] The last update of HS (harmonic focus) is more secure. It can seal the arteries up to 5mm in diameter.[12] Presently, a good percentage of surgeons believe that sutureless thyroidectomy is better than ligation suture technique[9] as in conventional method, more time is needed for applying secure, safe and non-slip knots.[4]

In the present study, there was lesser per-operative bleeding and postoperative drainage, which is consistent with the results of the study by Declared et al.[13] In our study, 72% patients in the test group had the surgery duration between 1-2 hours versus control group where 62% required more than 2 hours. The drains in the study group were removed within 24 hours in 68% patients while in the control group, 94.1 % of the drains were removed after 48 hours. These results are consistent with study by Ali et al. which showed a reduction in operation time and postoperative drainage in HS group versus conventional Knot tying group to be about 50%.[4] Ortega et al's. study confirmed a 15% to 20% reduction in the operation time.[14] In addition Shemen stated that using HS in thyroidectomy needs a smaller incision (4.5cm versus 5.5cm).[15] Vach et al. stated that, the histopathologist has no difficulty in examining the thyroid specimen removed by HS technique.[16] The reduction in postoperative drainage in test group is due to a reduction in intraoperative haemorrhage as the minor vessels are more secured leading to less postoperative drainage.[8]

The major problem in thyroid surgery is the recurrent laryngeal nerve injury and hypocalcaemia. The important aspect of using the HS device is the fear due to lateral thermal damage.[17] In the current study only one patient from both groups each, developed stridor due to bilateral recurrent laryngeal nerve injury. The patient in HS group needed tracheostomy, which was removed after one year, after performing laser vocal cordotomy due to permanent damage. The other patient in CLS had transient injury. The rate of transient and permanent injury after thyroid surgery is 4% to 7% and 1% to 4% respectively.[18] In our study the figures in bilateral RLN with permanent damage were nearly equal. Although 20% patients of HS group developed hoarseness of voice which was higher than the group with ligation suture method (15.7%). This can be expected as the incidence of nerve paralysis is 3 to 4 times higher in patients where the nerve was not exposed than in patients where it was routinely exposed and identified.[19]

Regarding Hypocalcaemia, the percentage in both groups was nearly 12%. Our finding was statistically not significant and is similar to other studies as that of Cordon et al. who

compared harmonic scalpel to electrocautery and encountered transient hypocalcaemia varying from 5-15%. Permanent hypocalcaemia was encountered in 5% patients,[20] despite Emam's theory, that less heat produced by HS, so less impairment of blood supply to parathyroid gland and less percentage of hypocalcaemia.[21] Our results show no significant reduction in rate of hypocalcaemia post thyroid surgery.

Conclusion

Both HS and ligation suture were effective in thyroid surgery despite reduction in operation time and postoperative drainage in HS group. Both procedures are reasonably safe.

Limitation and Recommendations

1. The sample size was small. This could give a false estimate of the advantage of one technique over the other.

2. Post-operative pain was not considered

3. Haemostatic clips and haemostatic sponges were not used, specially near the danger area of RLN to avoid thermal damage of HS and slip ligatures.

4. An important factor is the added cost of the harmonic scalpel, which is expensive due to being a disposable instrument and its generator. But the advantage of the reduction in the surgery time can allow the surgeon to operate on more than one patient per list. More studies are required for assessment of the cost effectiveness of this device.

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